IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT:	He	GROUP ART UNIT:	1617
SERIAL NO.:	10/008,223	CONFIRMATION NO.:	4333
EXAMINER:	Webman	ATTORNEY DOCKET NO.:	3409/1/US (PC31297)
FILED:	December 5, 2001		

TITLE: RAPIDLY DISPERSING PHARMACEUTICAL COMPOSITION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

November 15, 2006

RESPONSE TO OFFICE ACTION

Sir:

In response to the Office action dated August 15, 2006, please enter the following remarks.

Claims 18, 20, 21, 23-37, and 39-53 are currently pending and stand rejected under 35 U.S.C. §103(a) as being unpatentable over Bolt et al., European Patent No. 396 335 in view of Harrison et al., U.S. Patent No. 6,086,909. Reconsideration is respectfully requested of this rejection.

The Office asserts that "Bolt et al. teach oral administration of a composition comprising a non-steroidal anti-inflammatory drug; (2) Bolt et al. teach that solid dosage forms, which are swallowed, such as tablets and capsules, provide accurate dosage and avoid taste problems; and (3) Harrison et al. teach that celecoxib is a non-steroidal antiinflammatory drug. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in producing an effective pharmaceutical

composition comprising celecoxib that provides accurate dosage and avoids taste problems."

Applicants respectfully assert that the Office has not established a prima facie case of obviousness, because the cited references would not have motivated one of skill in the art to prepare the claimed compositions. Indeed, **Bolt et al. teach away from the claimed compositions** adapted for swallowing without prior disintegration. It is true that Bolt et al. mention that solid dosage forms that are swallowed "provide accurate dosage and avoid taste problems," see page 2, lines 9-10. However, Bolt et al. go on to point out particular problems with such dosage forms:

> since [solid dosage forms which are swallowed] have to disintegrate in the gastrointestinal tract and the medicament has then to dissolve before it can be absorbed, absorption tends to be slower than from a suspension, and may be less than complete. Also, some patients have difficulty swallowing tablets and capsules, and there is a practical limit to the size, and therefore the dose, that can be swallowed.

See page 2, lines 10-13.

The Office asserts that "since taste problems are associated with chewable tablets, it is obvious to one of ordinary skill in the art to have swallowed the tablet." Applicants respectfully disagree. Bolt et al. describe in great detail how taste problems – if present – may be avoided in their chewable dosage forms. Bolt et al. do not give a single example of a composition according to their invention that is adapted for swallowing without prior disintegration and instead, every example they give is for either a chewable tablet or one that may be dispersed in water before oral administration. One of skill in the art provided with the teachings of Bolt et al. would **not** have been motivated to prepare a non-chewable tablet or other dosage form. Bolt et al. repeatedly remark on the reasons why their chewable or dispersible formulations are preferred over dosage forms that are swallowed:

> In general, chewable tablets are advantageous in that they combine the accuracy of dosage associated with tablets, with the optimum bioavailability of suspensions. They may also accommodate larger doses than swallow tablets or capsules.

See page 2, lines 19-21. Bolt et al. go on to mention the taste problems that may be present with chewable tablets, but then report that their invention is one way to solve the problem:

> [The acceptability of chewable tablets] is, however, reduced for bitter tasting medicaments, such as antibiotics, especially at higher doses, for example 500 mg and above. ... It has now been found that the inclusion of an effervescent couple in chewable tablets of bitter-tasting medicaments has surprising advantages with respect to palatability, in addition to assisting the break-up of the tablets in the mouth when chewed or sucked.

Nothing in Bolt et al. would have led one of skill in the art to prepare the claimed compositions adapted for swallowing without prior disintegration. The teachings of Bolt et al., taken as a whole, clearly teach away from such compositions. Nothing in Harrison et al. would lead one of skill in the art back to the claimed compositions, and thus the invention as defined by claims 18, 20, 21, 23-37, and 39-53 is patentable over Bolt et al. in view of Harrison et al.

The Applicants submit that the present invention is now in condition for allowance. Early allowance of all pending claims is respectfully solicited.

Respectfully submitted,

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